

## **REMARKS**

Claims 1-4, 7, 8, 11-20 and 52, 53 and 56 are currently pending in this application. Applicants thank the Examiner for withdrawing the rejections under 35 U.S.C. § 112, first and second paragraphs, and § 102(b) over Boschetti *et al.* (U.S. Patent No. 5,635,215) (“Boschetti”). However, Applicants respectfully request reconsideration of pending claims 1-4, 7, 8, 11-20 and 52, 53 and 56.

### **I. Rejections Under 35 U.S.C. § 103**

#### **A. Claims 1-4, 7, 8, 11-20, 52 and 54-55**

Claims 1-4, 7, 8, 11-20, 52, 53 and 56 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Boschetti (U.S. Patent No. 5,635,215) (Office Action, pages 2-6).

Applicants respectfully traverse this ground of rejection.

The U.S. Supreme Court has recently addressed the test for obviousness under 35 U.S.C. § 103. *KSR International Co. v. Teleflex Inc.*, No. 04-1350, 550 U.S. \_\_ (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's *rigid application* of the ‘teaching, suggestion, motivation’ test (“the TSM test”) in determining obviousness in the particular case in question. *Id.*, *slip op.* p. 11. According to the Supreme Court, the correct standard to apply is set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). *Id.*, *slip op.* p. 2. However, the *KSR* decision indicated that while the TSM test is not the sole method for determining obviousness, it may still be a factor. *Id.* *slip op.* p. 14 (“When it first established [the TSM test], the Court...captured a helpful insight.”). Indeed, on May 3, 2007, the Deputy Commissioner of Patents circulated a memorandum to the Technology Center Directors (“USPTO Memorandum”) pointing out that the TSM test was not completely abolished in *KSR*.

The *Graham* factual inquiries, which establish a guide for determining obviousness, are: (1) determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) resolve the level of ordinary skill in the pertinent art; and (4) evaluate any evidence of secondary considerations. *KSR, slip op.* p. 2 (citing *Graham*, 383 U.S. at 15-17).

The instant claims are not obvious because the microspheres disclosed in Boschetti differ from microspheres recited in the instant claims. Furthermore, the scope and content of Boschetti does not provide a reason that would have prompted one of ordinary skill in the art to modify the teachings of Boschetti to arrive at the methods of the instant claims.

First, the instant claims are not obvious over Boschetti because they differ from the scope and content of Boschetti.

In *KSR*, the Supreme Court noted the significance of the specific facts in question. Indeed, the District Court found that the invention at issue was simply a combination of two known elements from the prior art. *KSR, slip op.*, p. 20. Once these specific findings were made, the Court then determined whether it was obvious to combine the teaching of the prior art to arrive at the claimed invention. *Id.* Thus, the threshold issue to be resolved is the differences between the claims at issue and the prior art.

This instant case is not a simple combination of known elements. Instead, the claims at issue relate to a novel injectable composition suitable for tissue bulking comprising swellable, substantially spherical microspheres comprising (1) an anionic polymer that is (2) crosslinked in an amount of from about 0.5% to about 20% and can (3) increase its weight by at least about 20 times its original dry weight upon contacting water.

The Examiner opines that Boschetti

teaches the spherical particles herein and [a] suspension composition comprising the same used for injection into tissue. The particles are made of a hydrophilic acrylic copolymer, and in [a] preferred embodiment, with about 10% of bifunctional

monomer....[and a] specific range of particle size within the range of 10  $\mu\text{m}$  to 2000  $\mu\text{m}$  are disclosed.

(Office Action, page 2). The Examiner correctly acknowledges, however, that Boschetti does not expressly disclose any of the following features recited by the claims:

- (1) that the polymer is an anionic polymer;
- (2) that the compositions would be injectable through needles of about 18-26 gauge;
- (3) the particular amount to the particles in the composition;  
and/or
- (4) the particular agents in the composition.

Nonetheless, the Examiner opines that it would have been *prima facie* obvious to a person of ordinary skill in the art to use an anionic polymer as the hydrophilic polymer and to adjust the particle size within the disclosed range so that the composition would be suitable for injection any needle required in the method.

The Examiner further alleges that “[a]nionic acrylic polymers [are] one of the three subgenus[es] with the in the genus of acrylic polymers (the other two are neutral and cationic). It is noted that Boschetti et al. prefer neutrol [*sic*] or cationic polymers (col. 2, lines 11-16), but claim 1 encompasses *all* hydrophilic acrylic copolymers (Office Action, page 3; emphasis added). Respectfully, the Examiner is incorrect. In particular, claim 1 explicitly recites that “the polymer is an anionic polymer.”

The Examiner further alleges that when “the reference discloses all the limitations of a claim except a property or function, the burden is shifted to [the] applicant for proof that the subject matter as taught or suggested by the reference does not possess the function herein claimed” (Office Action, page 5 (citing *Fitzgerald*, 619 F.2d (CCPA 1980); emphasis added).

Respectfully, however, Boschetti does not disclose all the limitations of independent claim 1. Indeed, the Examiner has provided no evidence that Boschetti teaches or suggests swellable microspheres comprising (1) an anionic polymer that is (2) crosslinked in an amount of from about 0.5% to about 20% and can (3) increase its weight by at least about 20 times its original dry weight upon contacting water, as recited in the claims.

Accordingly, the Examiner has provided no basis for the allegation that the instant claims are obvious over Boschetti.

Applicants respectfully point out that

Where applicable, the findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 USC 103 ground of rejection. *Dillon*, 919 F.2d at 693, 16 USPQ2d at 1901; *In re Mills*, 916 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990). Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings.

Manual of Patent Examination Procedure § 2144.08 (emphasis added).

While it is true that Boschetti *generally* teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization, the reference does not teach or make obvious the claimed swellable microspheres for tissue bulking comprising (1) an anionic polymer that is (2) crosslinked in an amount of from about 0.5% to about 20% and can (3) increase its weight by at least about 20 times its original dry weight upon contacting water. See, e.g., *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (Bd. Pat. App. & Int'f 1992) (prior art which provides only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it does not render the invention unpatentably obvious).

As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or can increase its weight by at least about 20 times its original dry weight

upon contacting water (*i.e.*, high water absorbing polymers). That is,

Furthermore, in *KSR* the references cited by the Examiner provided the patentee with all the elements of the claimed invention—the claimed invention was obtained merely by combining the references “like pieces of a puzzle.” *KSR, slip op.*, pp. 16-17. The instant case is distinguishable because Boschetti does not provide each element of the instant claims, namely, a swellable microsphere comprising (1) an anionic polymer that is (2) crosslinked in an amount of from about 0.5% to about 20% and can (3) increase its weight by at least about 20 times its original dry weight upon contacting water, as recited in the claims. Indeed, Boschetti discloses that cationic microspheres are preferred due to the ability to improve cell adhesion (see, *e.g.*, Col. 2, lines 11-37; Col. 3, lines 3-10; Col. 4, lines 57-60).

Therefore, because Boschetti, does not disclose the injectable composition of the instant claims, and because substantial differences exist between the instant claims and the scope and content of Boschetti, the instant claims are not obvious over this reference.

Further, the teachings of Boschetti would not prompt a person of ordinary skill to combine the elements to arrive at the instant claims.

In *KSR*, the Supreme Court emphasized that the “combination of familiar elements according to known methods is likely to be obvious when it yields no more than predictable results.” *KSR, slip op.* p. 12. However, the Court cautioned that “[f]ollowing these principles may be more difficult in other cases...because the claimed subject matter may involve more than the simple substitution of one known element for another....” *Id., slip op.* p. 14. Further, “it can be important to *identify a reason* that would have prompted a person of ordinary skill...to combine the elements in the way the claimed new invention does.” *Id., slip op.* p. 15 (emphasis added); *see also* USPTO Memorandum (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”).

As established above, the instant case involves more than the “simple substitution” of known elements in the prior art. Therefore, the Examiner must provide a reason why one of ordinary skill in the art would use the teachings of Boschetti and somehow arrive at the microspheres of the instant claims. The Examiner merely relies on the alleged overlap of certain elements of the microspheres of Boschetti with those of the instant claims. (Office Action, pages 2-5). However, the Examiner has provided no basis for the allegation that the instant claims are obvious over Boschetti, and the Examiner’s burden to support a rejection on the grounds of obviousness with explicit, articulate reasoning remains. *KSR, slip op.* p. 14 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also* USPTO Memorandum.

Further, because the cationic microspheres disclosed in Examples of Boschetti were *effective for vascular embolization*, one skilled in the art would have had no motivation whatsoever to use the claimed microspheres comprising *any anionic* polymer, *much less* an anionic polymer that is crosslinked in an amount of from about 0.5% to about 20% and can increase its weight by at least about 20 times its original dry weight upon contacting water for vascular embolization much less for tissue bulking, which is a completely unrelated field.

Thus, for at least these reasons, Applicants submit that Boschetti does not render any of 1-4, 7, 8, 11-20 and 52, 53, and 56. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**B. Claims 53 and 56**

Claims 53 and 56 were also rejected as allegedly being obvious over Boschetti in view of Tahara (U.S. Patent No. 5,298,570) (“Tahara”).

Applicants respectfully traverse this ground of rejection

As discussed above, in *KSR*, the Supreme Court cautioned that “the claimed subject matter may involve more than the simple substitution of one known element for another....” *Id., slip op.* p. 14. Further, “it can be important to *identify a reason* that would have prompted a person of ordinary skill...to combine the elements in the way the claimed new

invention does.” *Id.*, *slip op.* p. 15 (emphasis added); *see also* USPTO Memorandum (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”).

The instant case involves more than the “simple substitution” of known elements in the prior art. Therefore, the Examiner must provide a reason why one of ordinary skill in the art would combine the teachings of Boschetti and Tahara and somehow arrive at the microspheres of the instant claims. Instead, the Examiner merely states that the substitution of a sodium acrylate / vinyl alcohol copolymer would be *prima facie* obvious because sodium acrylate / vinyl alcohol copolymers “were known” (Office Action, page 4). Accordingly, the Examiner has provided no basis for the allegation that the instant claims are obvious over Boschetti in view of Tahara, and the Examiner’s burden to support a rejection on the grounds of obviousness with explicit, articulate reasoning remains. *KSR*, *slip op.* p. 14 (*citing In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also* USPTO Memorandum.

For at least these reasons, Applicants submit that claims 53 and 56 are non-obvious over Boschetti in view of Tahara. As such, Applicants respectfully request that this rejection be reconsidered and withdrawn.

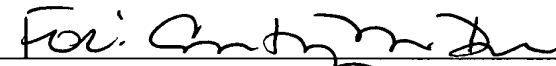
## **II. Conclusion**

In view of the foregoing amendments and remarks, Applicants respectfully submit that this application is now in condition for immediate allowance. *If the Examiner disagrees, Applicants respectfully request that the Examiner call the undersigned at the number listed below.*

A Petition for a Two (2) Month Extension of Time is submitted herewith, with provisions for the required fee, which extends the response period from April 19, 2007 to June 19, 2007. The Petition further authorizes the PTO to charge the estimated one month extension fee of \$60 to Jones Day Deposit Account No. 50-3013, which reflects Applicant’s Small Entity Status.

Applicants believe no other fees are due in connection with this response. However, if there are any other fees due, please charge them to Deposit Account 50-3013. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the Petition filed concurrently herewith, such an extension is requested and the fee should be charged to our Deposit Account. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,



Tamera M. Pertmer, Ph.D. (Reg. No. 47,856)

Date: June 19, 2007

*For:* Anthony M. Insogna (Reg. No. 35,203)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, NY 10017-6702  
(212) 326-3939